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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,611

11/22/2005

Atsutoshi Ikesue

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20529

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/557,611	<b>Applicant(s)</b> IKESUE ET AL.	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 13 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 November 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

This action is a supplemental non-final office action. The Office Action mailed April 17, 2008 is vacated. The claims submitted in the second preliminary amendment, dated December 28, 2005, are the set of claims used in preparing this office action.

### ***Election/Restrictions***

1. Applicant's election with traverse of group I and components of propyl gallate, di-*tert*-butylhydroxytoluene (BHT, paragraph [0020]) and ketoprofen in the reply filed on February 7, 2008 is acknowledged. The traversal is on the ground(s) that no appropriate explanation as to the existence of a serious search burden was given. This is not found persuasive because this application was filed as a National Stage Entry of a PCT application. As such, restriction and species elections are based on the special technical feature of the application and not on the showing of a search and examination burden. The feature in common between the groups was shown to be known in the art, and since a special technical feature must be a contribution over the prior art, a special technical feature does not link the various groups presented. Therefore the restriction and species election was proper.

While applicant is correct in asserting that claims 1 – 4 require the presence of both an alkyl ester of gallic acid and a phenolic radical scavenger, claims 8 – 11 only require the presence of one of these two ingredients. Therefore, the description of group

I given in the Requirement for Restriction/Election was of the broadest embodiment within the group, which does not require the presence of both an alkyl ester of gallic acid and a phenolic radical scavenger.

The requirement is still deemed proper and is therefore made FINAL.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 8 – 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 11/884,990 in view of Bertrand et al. The claims of the instant application recite a phenolic radical scavenger having a branched-chain lower alkyl group and/or an alkyl ester of gallic ester as an interleukin-1 $\alpha$  inhibitor, which can be a component in a transdermal formulation comprising and non-steroidal anti-inflammatory agent.

The claims of '990 recite a transdermal preparation for external use comprising a photosensitive NSAID, such as ketoprofen and a UV blocker having a high ability to migrate into the skin.

Bertrand et al. discloses topical pharmaceutical formulations comprising a NSAID, and a photo-protective agent (UV blocker; p 2, paragraph 2). Ketoprofen is unstable when exposed to daylight (p 3, paragraph 3). An antioxidant such BHA, BHT, palmitoyl ascorbate or tocopherol can be added to the composition to supplement the

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effects of the UV filter (p 7, paragraph 4). BHA and BHT are phenolic radical scavengers having a branched-chain lower alkyl group.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition as taught in '990, comprising an NSAID and UV blocking substance, and to add a phenolic radical scavengers having a branched-chain lower alkyl group such as BHT or BHA to the composition, taught by Bertrand et al. to supplement the effect of the UV filters of the photo-sensitive NSAID such as ketoprofen. That composition is encompassed by the claims of the instant application.

This is a provisional obviousness-type double patenting rejection.

4. Claims 8 – 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/570,785 in view of Bertrand et al. The claims of the instant application recite a phenolic radical scavenger having a branched-chain lower alkyl group and/or an alkyl ester of gallic ester as an interleukin-1 $\alpha$  inhibitor, which can be a component in a transdermal formulation comprising and non-steroidal anti-inflammatory agent.

The claims of '785 recite a transdermal preparation for external use comprising a photosensitive NSAID, such as ketoprofen and a UVA blocker that suppressed both phototoxicity and photoallergy of the anti-inflammatory drug having a high ability to migrate into the skin.

Bertrand et al. discloses topical pharmaceutical formulations comprising a NSAID, and a photo-protective agent (UV blocker; p 2, paragraph 2). Ketoprofen is unstable when exposed to daylight (p 3, paragraph 3). An antioxidant such BHA, BHT, palmityl ascorbate or tocopherol can be added to the composition to supplement the effects of the UV filter (p 7, paragraph 4). BHA and BHT are phenolic radical scavengers having a branched-chain lower alkyl group. Decomposition products of the active ingredient caused by light are implicated in sensitivity phenomena (p 2, paragraphs 4 and 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition as taught in '785, comprising an NSAID and UV blocking substance, and to add a phenolic radical scavengers having a branched-chain lower alkyl group such as BHT or BHA to the composition, taught by Bertrand et al. to supplement the effect of the UV filters of the photo-sensitive NSAID such as ketoprofen. That composition is encompassed by the claims of the instant application.

This is a provisional obviousness-type double patenting rejection.

### ***Claim Objections***

5. Claims 8 – 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5, from

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which claims 8 – 11 depend, recites an interleukin-1 $\alpha$  inhibitor consisting of at least one compound selected from the group consisting of a phenolic radical scavenger having a branched-chain lower alkyl group and an alkyl ester of gallic ester. In claims 8 – 10, the material of claim 5 is used as a component in a larger composition, further comprising other ingredients, a broader scope of compositions than that claimed in claim 5.

Therefore, claims 8 – 11 fails to further the limit the subject material of claim and are broader than the claim from which they depend.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 5 and 8 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertrand et al. (FR 2804024; English translation).

Bertrand et al. discloses compositions for topical application to the skin (a transdermal formulation for external application) that comprise at least one non-steroidal anti-inflammatory active agent, at least one photoprotective agent and an excipient or vehicle appropriate for external use (p 2, paragraph 3). The composition is intended to locally treat inflammation and/or joint pain (p 3). Preferred NSAIDS include ketoprofen (p 5, paragraph 2). Optional ingredients include antioxidants such as BHA and BHT



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(terbutyl paracresol; p 7, paragraph 4). Examples comprising ketoprofen and BHA are presented (p 8 – 11). Claim 5 of the instant application only requires the presence of one item selected from the group consisting of a phenolic radical scavenger having a branched-chain lower alkyl group (such as BHT) and an alkyl ester of gallic acid. Therefore, the transdermal formulation of Bertrand et al., consisting of BHT as the interleukin-1 $\alpha$  inhibitor as a component in a transdermal formulation with a non-steroidal anti-inflammatory analgesic, anticipates the claims of the instant application.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand et al. (FR 2804024; English translation) in view of Swingle et al. (1985).

Bertrand et al. discloses compositions for topical application to the skin (a transdermal formulation for external application) that comprise at least one non-steroidal anti-inflammatory active agent, at least one photo protective agent and an excipient or vehicle appropriate for external use (p 2, paragraph 3). The composition is intended to locally treat inflammation and/or joint pain (p 3). Preferred NSAIDS include ketoprofen (p 5, paragraph 2). Optional ingredients include antioxidants such as BHA and BHT (terbutyl paracresol; p 7, paragraph 4). Examples comprising ketoprofen and BHA are presented (p 8 – 11).

Bertrand et al. does not explicitly exemplify a composition comprising BHT and ketoprofen or disclose propyl gallate as a possible ingredient in the topical composition comprising ketoprofen.

Swingle et al. discloses that both BHT and propyl gallate are phenolic antioxidants that exhibit *in vivo* anti-inflammatory activity (p 113, section IV and table 1, p 114). The efficacy of these compounds as anti-inflammatory agents in different models of inflammation is presented in table 1 (p 114).

Swingle et al. teaches that BHT and propyl gallate possess antioxidant activity but also act as non-steroidal anti-inflammatory agents. As such, these compounds would be useful for the treatment of inflammation. Bertrand et al. discloses a composition comprising ketoprofen and an antioxidant such as BHA or BHT that is also useful for the treatment of inflammation. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising ketoprofen, BHT and propyl gallate as the prior art teaches each component as being useful for the treatment of inflammation. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

NMW